ATTACHMENT 8.0

SUMMARY OF SAFETY AND EFFECTIVENESS

Submitted by:

Vicki L. Drews
Baxter Healthcare Corporation
I.V. Systems Division
Route 120 and Wilson Road
Round Lake, IL 60073

Date of Submission:

August 3, 2000

Proposed Device(s):

Infusor SV
Infusor LV
Baxter Pain Management System

Comparison Device(s):

Infusor SV
Infusor LV
Painbuster Infusion System

Intended Use:

The intended use is the only modification being proposed for the currently marketed Baxter Infusor devices. The intended use of the stand alone devices will be expanded to include the continuous infusion of medication directly into an intraoperative site or subcutaneously for postoperative pain management, in addition the current intended use: slow, continuous intravenous, intra-arterial, subcutaneous or epidural administration of medications. When packaged in the kit configuration (Baxter Pain Management System), the intended use of the Infusor will be limited to use for this pain management indication. This intended use is consistent with the I-Flow Pain Management System.

Technological Characteristics:

There is no change in technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 5 2000

Ms. Vicki L. Drews
Manager, Regulatory Affairs
Baxter Healthcare Corporation
I.V. Systems Division
Route 120 & Wilson Road
Round Lake, Illinois 60073-0490

Re: K002380
Trade Name: Baxter Pain Management System
Regulatory Class: II and II
Product Code: FRN and MEB
Dated: August 3, 2000
Received: August 4, 2000

Dear Ms. Drews:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Susan Runner

for Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ATTACHMENT 10.0

INTENDED USE

The intended use of the proposed Infusor when packaged in the kit configuration (Baxter Pain Management System) will be continuous infusion of medications directly into an intraoperative site or subcutaneously for postoperative pain management, the same indication cleared for the I-Flow Pain Management System. In addition to this use, the intended use of the stand alone Infusor Devices will include the continuous intravenous, intra-arterial, subcutaneous or epidural administration of medications, the same indication cleared for the current line of Baxter elastomeric infusion pumps.

Julie Hibbard for Pat Cricenti

(Division Sign-Off)
Division of Dental, Infection Control,
General Hospital Devices
Number K002380